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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,842	10/12/2001	Rajinder S. Ranu	TagawaGene25Full	3997

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Santangelo Law Offices, P.C.
Third Floor
125 South Howes
Fort Collins, CO 80521

EXAMINER
KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,842	Applicant(s) RANU, RAJINDER S.	
	Examiner Russell Kallis	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *4-6 and 9-15* is/are withdrawn from consideration.

5)☐ Claim(s) 1 is/are allowed.

6)☒ Claim(s) *1-3,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-3 and 7-8 in Paper No. 6 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims an isolated DNA molecule consisting of SEQ ID NO: 1; an isolated polynucleotide comprising degenerate variants of SEQ ID NO: 1; an isolated polynucleotide comprising nucleotide sequence at least 80% identical to SEQ ID NO: 1; and an isolated polynucleotide comprising a nucleotide sequence defined by a PCR primer pair of SEQ ID NO: 2 and 3.

Applicant describes SEQ ID NO: 1, 2, and 3.

Applicant does not describe degenerate variants of SEQ ID NO: 1 or any polynucleotide comprising a nucleotide sequence defined by PCR primer pair SEQ ID NO: 2 and 3, other than SEQ ID NO: 1.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Claims 2-3 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule consisting of SEQ ID NO: 1 and an isolated polynucleotide comprising SEQ ID NO: 1, does not reasonably provide enablement for degenerate variants of SEQ ID NO: 1 or any polynucleotide comprising a nucleotide sequence defined by PCR primer pair SEQ ID NO: 2 and 3, other than SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims an isolated DNA molecule consisting of SEQ ID NO: 1; an isolated polynucleotide comprising degenerate variants of SEQ ID NO: 1; an isolated polynucleotide comprising nucleotide sequence at least 80% identical to SEQ ID NO: 1; and an

isolated polynucleotide comprising a nucleotide sequence defined by a PCR primer pair of SEQ ID NO: 2 and 3.

Applicant teaches an isolated polynucleotide comprising SEQ ID NO: 1 defined by PCR primer pair of SEQ ID NO: 2 and 3 (pages 39-40).

Applicant does not teach degenerate variants of SEQ ID NO: 1 or any polynucleotide comprising a nucleotide sequence defined by PCR primer pair SEQ ID NO: 2 and 3, other than SEQ ID NO: 1.

The isolation of DNA sequences having 80% sequence identity or comprising degenerate variations of a particular polynucleotide sequence introduces an element of unpredictability. The limitation is introduced in finding homologous regions that would adequately enable PCR amplification or southern hybridization and would entail using either degenerate primers or probes with limited sequence identity. Thus the screen for degenerate sequences or sequences with limited sequence identity would isolate many genes other than those of the instant claims. Fourgoux-Nicol *et al.*, 1999, Plant Molecular Biology, Vol. 40; pp. 857-872 teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2nd paragraph). Fourgoux-Nicol *et al.* also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). The inherent

unpredictability in isolating a degenerate sequence with some known function is illustrated in an example where a small number of changes to the coding region for a strict desaturase resulted in an enzyme with a hydroxylase activity and suggests that in general a small number of changes to a polynucleotide can account for a broad range of functional divergence (Broun P. *et al.* Science Vol. 282; 13 November 1998, pp. 1315-1317; Abstract lines 4-6 and p. 1317 column 1, lines 37-56).

Isolating PCR products comprising desired genes encoding desired products while conducting early PCR cycles or all PCR cycles under low stringency conditions gives rise to promiscuous annealing of primer and template and thus produces discreet yet unpredictable reaction products because of permissive mismatches. Thus the PCR reaction products created under low stringency are most likely to encode undesired genes. (Welch J. *et al.* Nucleic Acids Research, December 25, 1990; Vol. 18, No. 24; pp. 7213-7218; on page 7214 column 2 2nd paragraph).

Given the lack of guidance for isolating any other polynucleotides comprising sequences with at least 80% sequence identity to SEQ ID NO: 1, or degenerate variants of SEQ ID NO: 1, or any non-exemplified polynucleotide defined by the PCR primer pair of SEQ ID NO: 2 and 3 other than SEQ ID NO: 1, the breadth of the claims, and given the unpredictability in the art, undue trail and error experimentation would be needed by one skilled in the art to isolate a multitude of non-exemplified polynucleotides, and evaluate their use or the use of their encoded products. Therefore, the invention is not enabled for the scope set forth in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Boeshore M. *et al.* WO 96/21027 PCT publication date July 11, 1996 (see attached sequence report).

Applicant broadly claims an isolated polynucleotide comprising degenerate variants of SEQ ID NO: 1; and an isolated polynucleotide comprising a nucleotide sequence defined by a degenerate PCR primer pair of SEQ ID NO: 2 and 3.

Boeshore teaches an isolated degenerate variant of SEQ ID NO: 1 and inherently teaches a polynucleotide isolated by PCR primer pair of SEQ ID NO: 2 and 3, given the shared sequence identity with SEQ ID NO: 2 (see attached sequence report AAT33139), and given the promiscuous nature of PCR amplification especially when using degenerate primers that is well known in the art, and the absence of any limitation in the claim that sets forth a defining characteristic of the amplified product other than the sequence identity of the primers used to conduct the amplification. Thus, the reference teaches all the limitations of Claims 2-3 and 8.

Claims 1 and 7 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated DNA molecule consisting of SEQ ID NO: 1 and an isolated polynucleotide comprising a nucleotide sequence at least 80% identical to SEQ ID NO: 1.

Claims 2-3 and 7-8 are rejected.

Claim 1 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
April 2, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~1800~~ 1638